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Radiology/Nuclear Medicine
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Steve Phurrough, M.D., M.P.A.
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Centers for Medicare & Medicaid Services
7500 Security Blvd., Mail stop C1-09-06
Baltimore, MD 21244

Re: Request for National Coverage Determination for FDG PET for Suspected Infection and Inflammation

Dear Dr. Phurrough:

We submitted a letter dated February 27, 2007 requesting that the Centers for Medicare & Medicaid Services (CMS) establish a national coverage policy for positron emission tomography (PET) with ^{18}F-labeled Fluorodeoxyglucose (FDG) for the diagnostic evaluation of patients with suspected infectious and inflammatory disorders. Based on our meeting with the Coverage and Analysis Group on May 2, 2007 we would like to modify our request to focus on those indications and beneficiaries where FDG PET has the greatest clinical benefit for Medicare beneficiaries.

Summary

This letter narrows our previous request for a national coverage determination (NCD) by focusing on three specific conditions for which FDG-PET's diagnostic efficacy is particularly well-established: 1) chronic osteomyelitis; 2) infection associated with hip arthroplasty; and 3) fever of unknown origin. For each indication the letter details specific criteria for when we believe FDG PET is warranted. Each of these conditions disproportionately afflict the Medicare population.

Based on the peer-reviewed scientific literature and our own extensive clinical experience, FDG-PET imaging provides information that is of great importance in the diagnosis and management of patients with a variety of infectious and inflammatory disorders. Two recent review articles, by Zhuang et al. (1) and Vos et al. (2), respectively, summarize these considerable benefits.

National Coverage Decision Request

The clinical basis of this request is that FDG-PET is significantly more sensitive and specific for detecting infection and inflammation than are conventional imaging techniques. High-resolution tomographic images acquired with PET are superior to those provided by conventional nuclear medicine techniques for assessment of infection (e.g., scintigraphy with ^{67}Ga citrate or with either ^{111}In- or ^{99m}Tc-labeled leukocytes). In addition, tomographic images generated by PET allow direct comparison with corresponding structural imaging modalities, such as CT and MRI. The combined modality of PET/CT can determine the precise location of the sites of infection or inflammation. Structural imaging techniques frequently provide non-specific results in the assessment of patients with infectious and inflammatory disorders.

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As outlined below we request Medicare coverage for the following indications. The request includes clinical criteria to limit over utilization for FDG PET for infection and inflammation. For most beneficiaries routine tests will be used. For a portion of the beneficiaries who cannot be diagnosed with routine tests a FDG PET is required.

Chronic Osteomyelitis

Published, peer-reviewed scientific literature demonstrates that FDG-PET is highly effective in diagnosing suspected chronic osteomyelitis. It is not only the most sensitive imaging modality for detecting chronic osteomyelitis, but also has a greater specificity than gallium scintigraphy, radiolabeled leukocyte scintigraphy, bone scintigraphy, or MRI. (2-6)

FDG PET should be covered for suspected chronic osteomyelitis in patients with
1. previously documented osteomyelitis with suspected recurrence or
2, symptoms of osteomyelitis for more than six weeks (including diabetic foot ulcers)

FDG PET or PET/CT would replace bone, leukocyte, and/or gallium scintigraphy that are now used in the evaluation of these patients.

Infection associated with hip arthroplasty

Infection associated with hip arthroplasty is very common—1% to 4% following first-time arthroplasty; and approximately 25% following revision arthroplasty. However, establishing accurate diagnosis of infection associated with hip arthroplasty has always been particularly challenging, and unsuccessful in most settings. The peer-reviewed literature strongly supports the effectiveness of FDG-PET for the detection of such infection. (7-10)

FDG PET should be covered for investigation of patients with suspected infection of hip prosthesis

FDG PET or PET/CT would replace bone, leukocyte, and/or gallium scintigraphy that are now used in the evaluation of these patients.

Fever of Unknown Origin

FDG is highly valuable in evaluating patients with fever of unknown origin (FUO). FDG accumulates in infections, malignancies and inflammatory diseases—the three major etiopathologies of FUO. As a tracer that localizes in many of the causes of FUO, it can replace leukocyte, and/or gallium scintigraphy in this setting. (9, 11-13).

FDG PET should be covered for the following patients for fever of unknown origin:
A febrile illness of >3 weeks' duration, a temperature of >38.3 degrees C on at least two occasions, and diagnosis uncertain after a thorough history, physical examination, and one week of appropriate investigations.

Conclusion

In summary, FDG-PET has been shown to be clinically effective in diagnosing suspected chronic osteomyelitis, infection associated with hip arthroplasty, and fever of unknown origin. We strongly urge CMS to establish a coverage policy for these indications.

We appreciate your attention to this issue. If we can provide any additional information, please contact us.

Sincerely,

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